

consultation with the Office of New Drugs and the Office of Surveillance and Epidemiology. It also calls for a report to Congress on the assessment of that coordination.

The requirement that these two offices be consulted doesn't necessarily change the status quo. The Office of Surveillance and Epidemiology is still just a consultant to the Office of New Drugs, and the Office of New Drugs decides—and will continue to decide—what, if any, action will be taken to address a safety issue. But I hope that requiring that the office responsible for postmarketing surveillance be at the table would encourage FDA to better define the role of this office on drug safety matters and give this office a greater voice, albeit a limited one.

Last fall, the Government Accountability Office reported that the Office of New Drugs typically sets the agenda and chooses the presenters at FDA's scientific advisory meetings. The GAO recommended that the role of the Office of Surveillance and Epidemiology be clarified. After all, this office is the expert on postmarketing safety matters.

This week, Senator BAUCUS and I sent a letter to the FDA to express concerns regarding an upcoming advisory committee meeting on Avandia. As usual, the Office of New Drugs is setting the agenda here. We pointed out to the FDA that it doesn't make sense that it is the drug approval office and not the postmarketing safety office that controls the advisory committee meeting convened for the purpose of discussing postmarketing safety matters.

In addition to the provisions I have mentioned so far, both the Senate and House bills would give FDA the much needed authorities to require labeling changes and postapproval studies; however, the House bill includes additional provisions outside of the risk evaluation and management strategy process that is established under both bills.

The House bill specifically enables the Secretary to initiate action on drug labeling and postapproval studies. For example, outside of the risk evaluation and management strategy process, the Secretary may require a manufacturer to conduct postapproval research to assess or identify potential health risks.

Another provision that would improve transparency at the FDA is a provision in the Senate bill that requires FDA to post on its Web site, the "action package" for the approval of a new drug within 30 days of approval. That action package would contain any document generated by the FDA related to the review of the drug application, including a summary review of all conclusions and, among other things, any disagreements and how they were resolved.

Further, in light of the many allegations that FDA safety reviewers are sometimes coerced into changing their scientific findings, I believe it is crit-

ical that the following provision in S. 1082 survives the legislative conference process—the provision that states that a scientific review of a drug application must not be changed by FDA managers or the reviewer once it is final.

S. 1082 also requires FDA to seek outside expert opinions on drug safety questions at least two times a year from its Drug Safety and Risk Management Advisory Committee and other advisory committees.

Another important provision in S. 1082 is a requirement that FDA establish and make publicly available clear, written policies on the review and clearance of scientific publications by FDA employees.

Some of the stronger provisions regarding the expansion of the clinical trial registry come from the House bill. While both bills address clinical trial registration, the House bill adopts a much broader definition of applicable clinical trials. "Thus, information about many more trials would be made publicly available through the Internet under the House bill."

Clinical trial registries serve an important function—they foster transparency and accountability in health-related research and development by ensuring that the scientific and medical communities and the general public have access to basic information about clinical trials. Mandatory posting of clinical trial information would help prevent companies from withholding clinically important information about their products.

I have heard from some scientists that they can't disclose the findings of their studies because the data belongs to the manufacturer. It is up to the manufacturer to decide if and when the results would be published, and those results don't always see the light of day.

But scientists need access to all of the evidence to conduct a full and independent review of a product's safety. However, we know that relevant data are not always made available for further review by independent scientists. While the House bill does not require manufacturers to share its data with other scientists, it does require the sponsor of a study to report whether or not agreements were made restricting individuals from discussing or publishing trial results.

In addition, for FDA's new authorities to be effective, there has to be strong civil monetary penalties. In May, I also offered amendment No. 998 to S. 1082. That amendment passed.

Amendment No. 998 provides for the application of stronger civil monetary penalties for violations of approved risk evaluation and mitigation strategies.

While significant monetary penalties may be imposed under the House bill for continuous violations, the minimum penalty for a violation under the Senate bill would be higher because of my amendment. We need to make sure that we're giving FDA, the watchdog,

some bite to go with the bark. If monetary penalties are nothing more than the cost of doing business, you won't change behavior. More importantly, you can't deter intentional bad behavior.

In closing, I would like to thank Senators KENNEDY and ENZI and Congressmen DINGELL and BARTON for their tremendous efforts on these bills. We have an opportunity to reform, improve, and reestablish the FDA as the gold standard for drug safety. If Congress is going to make meaningful changes to the FDA to increase transparency and accountability, it is critical that the provisions I have discussed today make it into the bill that comes out of conference. To do less would deny the American people safer drugs when they reach into their medicine cabinets.

#### HONORING THE PRESIDENT OF THE REPUBLIC OF CYPRUS

Mr. BAYH. Mr. President, I believe that Members of the Senate and House of Representatives will be pleased that two of our distinguished former colleagues were this month honored by President of the Republic of Cyprus, Tassos Papadopoulos.

In ceremonies on July 3 at the Presidential Palace in Nicosia, the capital of Cyprus, President Papadopoulos bestowed on Senator Sarbanes and Congressman Brademas the Grand Cross of the Order of Makarios III.

John Brademas, who served for 22 years as Representative in Congress from the District centered in South Bend, IN, was author or coauthor of much of the legislation enacted during those years in support of schools, colleges, and universities; libraries and museums; the arts and the humanities. In his last 4 years, he was Majority Whip of the House of Representatives.

Paul Sarbanes served in the House of Representatives for 6 years and the Senate for 30 years. As chair of the Senate Committee on Banking and Urban Affairs, he was principal author of the Sarbanes-Oxley Act of 2002, to ensure integrity in corporate governance.

Both John Brademas and Paul Sarbanes were Rhodes scholars and so studied at Oxford University, from which both earned degrees. John Brademas also graduated from Harvard University and Paul Sarbanes from Princeton University and the Harvard Law School.

John Brademas was the first native-born American of Greek descent elected to Congress, House or Senate; Paul Sarbanes was the first Greek-American elected to the Senate. I note that his son, JOHN SARBANES, was last November in Maryland elected to Paul's former seat in the House of Representatives.

While in Nicosia, both former Senator Sarbanes and former Congressman Brademas also visited the HSPH-Cyprus International Initiative for the

Environment and Public Health, a program associated with the Harvard School of Public Health.

At this point in the RECORD, I ask unanimous consent that the remarks of President Papadopoulos of the Republic of Cyprus at the Presidential Palace, Nicosia, Cyprus, on July 3, 2007, be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

REMARKS OF PRESIDENT TASSOS  
PAPADOPOULOS OF THE REPUBLIC OF CYPRUS

Senator Sarbanes; Congressman Brademas; Your Eminence, Archbishop Chrysostomos; Your Eminence, Archbishop Demetrios; Ambassador Schlicher; distinguished friends and guests,

It gives me great pleasure to welcome you tonight at the Presidential Palace in order to pay tribute to two long-standing and unwavering supporters of the people of the whole of Cyprus, Senator Paul Sarbanes and Congressman John Brademas.

I have had the privilege of knowing both these distinguished gentlemen for many years and I consider them to be among the most ardent, tireless and unflinching supporters for the just cause of Cyprus in the United States.

Senator Sarbanes and Congressman Brademas ably represented the people in their respective constituencies for decades, as well as successfully advancing the aspirations and objectives of the Hellenic American Community. I can think of no other two people who have done more for the nurturing of closer bonds between the people of Cyprus and the United States of America. I have always held the view and have declared on several public occasions that the first loyalty of Americans of Greek origin is to their host country, the United States of America. When, however, the best interests of the United States and the rules of international law and practice are not incompatible with the special interests of Greece and of Cyprus, we hope and expect that they will lean towards and publicly remember their ethnic roots. Both gentlemen have admirably honoured these principles.

For all these reasons, the Government of the Republic of Cyprus has decided to pay tribute to their life-long commitment to the Rule of Law, "justice for Cyprus", for the condemnation of the Turkish invasion of Cyprus, for the end of the occupation of Cyprus soil by Turkish troops, for the end of the massive violations of human rights in Cyprus by Turkey and for promoting a just, functional and lasting solution to the Cyprus issue.

JOHN BRADEMAs

John Brademas was born in Mishawaka, Indiana, of Greek parentage. He was elected to the United States Congress in 1958 as a Representative of Indiana's Third District, thus becoming the first U.S.-born Greek-American to be elected to the United States Congress and paving the way for, among others, Paul Sarbanes, Paul Tsongas and Mike Bilirakis.

He represented his district for twenty-two years (1959-1981), the last four as Majority Whip for the Democratic Party. Upon leaving Congress, Dr. Brademas served as President of New York University from 1981 to 1992 and has since been President Emeritus. He has been integral in establishing a close-knit relationship between Cyprus and New York University, examples of which are the current excavations in Yeronisos under Professor Joan Connelly and the Cyprus Global Professorship on History and Theory of Jus-

tice, which I will have the honour of inaugurating in September.

PAUL SARBANES

Paul Sarbanes was born in Salisbury, Maryland, of Greek parents. After serving in the Maryland House of Delegates for four years, he was elected to the United States Congress in 1970 and served in the House of Representatives for six years.

In 1976 he was elected to the United States Senate for the State of Maryland and was re-elected four more times, serving for a total of thirty years, before retiring this January. As Chair of the Senate Banking and Urban Affairs Committee in 2001-02, he was the main architect of the 2002 Sarbanes-Oxley Act, which effectuated one of the most significant changes to United States Securities laws in over 70 years.

As impressive as their domestic record, it is the steadfast support for the just cause of Cyprus of Senator Sarbanes and Congressman Brademas which brings us here today.

Immediately after the Turkish invasion of 1974, John Brademas and Paul Sarbanes, with the help of the late Congressman Benjamin Rosenthal of New York and Senator Thomas Eagleton of Missouri, who recently passed away, led the successful effort of enforcing an arms embargo against Turkey. As Dr. Brademas put it himself, Paul Sarbanes and he were not the Greek lobby, but the "rule of law lobby".

This last notion forms the cornerstone of their support towards Cyprus. Both men have for many years advocated for a just solution to the Cyprus problem, not only because it is a Hellenic issue, but because it is essentially a rule of law and human rights issue, under United States law. Only a solution based on the relevant Security Council Resolutions and in accordance with the principles of international law, as well as the *Acquis Communautaire* of the European Union, can secure a permanent, viable and stable solution, which will benefit all Cypriots. Such a solution, which is not tailor-made for the satisfaction of outside parties, will enhance the stability of the Eastern Mediterranean and is conducive to the interests of the United States.

THE RULE OF LAW

John Brademas and Paul Sarbanes consistently advanced the cause of Cyprus throughout their political careers. In so doing, they have been the embodiment of values cherished by America, such as the rule of law, respect for human rights and democratic governance, which are, alas, all too often swept aside for reasons of political expedience.

Tonight's honourees, have been exceptional leaders of the Greek-American Community. I would be remiss if I did not dedicate a few words towards the Hellenic diaspora in the United States. The President of the Cyprus Federation of America, Mr. Peter Papanicolaou, is amongst us today, so I take this opportunity to convey through him the sincere appreciation of the Cypriot people for the Community's tireless support and to urge you, dear Peter, to continue with your efforts until Cyprus is free and freely reunified, in its territory, society, institutions and economy.

I would also like to welcome again to Cyprus the spiritual leader of the community, His Eminence, Archbishop Demetrios, and to thank him for his efforts to stop the pillage and destruction of Cyprus' religious and cultural heritage in the occupied area.

Before I conclude my remarks, I wish to once again express the heartfelt gratitude and appreciation of the Government and people of Cyprus to Paul Sarbanes and John Brademas for their unwavering commitment, all these years, and to wish them the best of luck for all their future endeavors.

Mr. BAYH. Mr. President, at this point in the RECORD, I ask unanimous consent that the remarks of former Congressman Brademas on this occasion be printed in the RECORD. Senator Sarbanes responded extemporaneously on this occasion.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

REMARKS OF DR. JOHN BRADEMAs PRESIDENT  
EMERITUS, NEW YORK UNIVERSITY AND  
FORMER MEMBER, INDIANA, 1959-1981,  
UNITED STATES HOUSE OF REPRESENTATIVES

President Papadopoulos; Your Eminence, Archbishop Chrysostomos; Your Eminence, Archbishop Demetrios; Ambassador Schlicher; distinguished guests and friends all, I want to express to you, Mr. President, my deepest appreciation for the high honor that you do my colleague and valued friend, Senator Paul Sarbanes, and me with the award of the Grand Cross of the Order of Makarios III.

I want to recognize as well Dr. Phillip Mitsis, Alexander S. Onassis Professor of Hellenic Culture and Civilization and Professor of Classics at New York University, and his wife, Sophia Kalantzakos, a Member of the Parliament of Greece.

Let me here also thank the distinguished Ambassador of the United States to the Republic of Cyprus, His Excellency, Ronald L. Schlicher, for having this week so graciously received Senator and Mrs. Sarbanes, my wife and me.

It was nearly one year ago, on September 8, 2006, that I had the privilege of welcoming to New York University the distinguished President of the Republic of Cyprus, His Excellency, Tassos Papadopoulos, and now I am pleased to be in the country he so faithfully serves as leader.

I hope, Mr. President, and ladies and gentlemen, you will allow me a few words to say why this honor is so meaningful to me.

As most of you know, I am the first native-born American of Greek origin elected to the Congress of the United States—my late father was born in Kalamata.

I was for 22 years a Member of the House of Representatives, from the State of Indiana.

In Congress, I was a member of the committee with responsibility for education legislation and so helped write all the laws enacted during those two decades and two years to support schools, colleges and universities; libraries and museums; the arts and the humanities. And in my last four years, I served as the Majority Whip of the House of Representatives, part of the Leadership of the Democratic Party.

In 1981 I became president of New York University or, as we call it, NYU, the largest private university in my country. I am now president emeritus.

SENATOR PAUL SARBANES

I am so pleased that my distinguished friend, United States Senator Paul Sarbanes of Maryland, is here with his lovely wife, Christine, and am, of course, delighted that my brilliant and beautiful physician wife, Mary Ellen, has joined me for this ceremony.

And I want to thank my dear cousin, Anna Bredima-Savopoulos, Counsel for the Union of Greek Shipowners, for having flown here from Athens to be on hand for this ceremony. I am very proud of Anna's accomplishments.

Paul Sarbanes, as you know, for many years a leading member of the United States Senate and, indeed, the first Greek-American elected to the Senate, and a valued ally in the struggle for justice for Cyprus, is someone I have often described as "a modern Pericles".

I am delighted that Paul's son, John Sarbanes, was last November elected to represent Paul's former constituency in the

House of Representatives even as I'm pleased to say that only a few weeks ago, Michael Sarbanes, another son of Paul and Christine, has announced his candidacy for the presidency of the City Council of Baltimore. Obviously, politics runs in the Sarbanes family!

I'm glad, too, to welcome some other friends from my days in Washington, including the distinguished former Ambassador of Cyprus to the United States, Andreas Jacovides, and his wife, Pamela, as well as two great champions of the Hellenic cause in my country and, indeed, the world, Andrew Athens and Andrew Manatos.

I'm pleased also that two vigorous voices of the Cypriot community in the United States are here today, Phillip Christopher and Panicos Papanicolaou.

I'm glad as well to greet a colleague from New York University, an outstanding scholar, Professor Joan Breton Connelly, leader of the excavation of Yeronisos Island and of an international team there. Professor Connelly has just published a magnificent book, *Portrait of a Priestess: Women and Ritual in Ancient Greece*, which has won splendid reviews in the New York Times and New York Review of Books.

And I must salute that eminent archaeologist, Professor Vassos Karageorghis, director of the Anastasios G. Leventis Foundation.

#### LINKS WITH CYPRUS

I have still other links with Cyprus.

I serve on the international advisory counsel of The Pharos Trust, that splendid chamber of cultural activity in Cyprus, led by Garo Keheyan. And as a graduate of Harvard University, I'm pleased also to serve on the Executive Council of the Cyprus International Initiative for the Environment and Public Health—Harvard School of Public Health. And as I'm recalling connections, I'm glad again to see a respected Cypriot businessman, George Paraskevaides, and his wife, Thelma.

Tonight I recall that it was nearly ten years ago in June of 1998, that I had the privilege of visiting the University of Cyprus and being received by its distinguished Rector, Professor Dr. Miltiades Chacholiades, and of addressing members of the Cyprus Chamber of Commerce & Industry and Cyprus American Business Association.

Of course, particularly meaningful, all the more so in light of the decoration Paul Sarbanes and I are today receiving, is the trip Paul and I made in August 1977 when we came here for the funeral of the great leader of the Cypriot people, His Eminence, Archbishop Makarios.

The connection, however, with Cyprus of which some of you may be most aware is the one of which I shall say a few words now.

In 1967, when a group of Greek colonels overthrew young King Constantine of Greece, I, the only Greek-American in Congress, sharply attacked the coup. I refused to visit Greece or go to the Greek Embassy in Washington and I publicly opposed U.S. military aid to Greece, arguing that as Greece was a member of NATO, which championed freedom, democracy and the rule of law, none of which values the Greek military junta supported, the United States should not be sending them arms.

#### TURKISH INVASION OF CYPRUS

In July 1974, the junta attempted to overthrow Archbishop Makarios, President of Cyprus, an action that brought the downfall of the colonels but also triggered two invasions of Cyprus by Turkish armed forces, forces equipped with weapons supplied by the United States, a legal "No-No".

So I led a group of several Members of the House of Representatives, including then Representative Sarbanes, to call on the Secretary of State, Henry Kissinger, and we told

him that as American law mandated an immediate halt to further shipment of arms to any country using American weapons for other than defensive purposes, he should enforce the law and impose an embargo on further U.S. arms to Turkey.

As this was the same week that Richard Nixon resigned the presidency, I reminded Secretary Kissinger that the reason Mr. Nixon was on his way in exile to California was that he had not respected the laws of the land or the Constitution of the United States.

"You should do so," I told Kissinger.

He and the new President, Gerald R. Ford, refused to enforce the law, and, therefore, we in Congress did.

I remind you that the United States has a separation-of-powers constitutional system, not a parliamentary system! So in 1974, Congress voted an embargo on sending further American weapons to Turkey. As I have from time to time heard criticisms, in respect of the role of "the Greek lobby" in Congress, I observe that when we voted the embargo on further U.S. arms to Turkey, there were only five of us of Greek origin in Congress, all in the House of Representatives: John Brademas, Paul Sarbanes, Peter Kyros, Gus Yatron—all Democrats, all of whom supported the embargo—and one Republican, Skip Bafalis, who voted against it. There were at that time no Americans of Greek descent in the Senate.

Accordingly, this so-called "Greek lobby" was effective because of the validity of our arguments and, if I may say so, of our work to generate support for our position not only among Greek-Americans across the country but among other Americans who shared our views.

#### "THE RULE OF LAW LOBBY"

We were "The Rule of Law Lobby"!

I shall not here take time to review with you my subsequent experience when President Jimmy Carter, to my distress, as I generally supported his Administration, called on Congress to support lifting the embargo on Turkey despite the fact that there had been no action to resolve the Cyprus question.

Here I must pay tribute to my friend of many years, Costa Carras, founder in London of "Friends of Cyprus" who has continued to call attention to the issue that concerns us all—justice for Cyprus. In my view, finding a just resolution for Cyprus is an indispensable requirement as the European Union considers the application for membership of Turkey even as I believe there are other commitments Turkey must make if it wishes to join the EU.

First, of course, is that Turkey comply with the so-called Copenhagen criteria, which include respect for minorities, respect for human rights, respect for decent treatment of peoples.

Certainly it is not rational that a European Union member-state militarily occupy another EU member-state, and Cyprus is now a member of the European Union.

As today there are over 40,000 Turkish armed forces in Cyprus, their continued presence, if Turkey were in the European Union, would be an offense to common sense.

I add that there are an estimated 160,000 Turkish settlers in northern Cyprus while there are only 100,000 Turkish Cypriots!

A second point: It is also unreasonable for one member of the European Union to refuse to give diplomatic recognition to the existence of another member, and as we all know, Turkey has refused to recognize the Republic of Cyprus.

So these then are two of the conditions—removal of Turkish troops and diplomatic recognition of Cyprus—that it seems to me

must be met by the Government of Turkey as it seeks to join the European Union and take advantage of the benefits of such membership.

If a just settlement on Cyprus is one issue related to Turkey's desire to join the European Union, there is another of which I shall say a word.

#### ATTACKS ON ECUMENICAL PATRIARCHATE

Three years ago, His Eminence, Archbishop Demetrios, Primate of the Greek Orthodox Church in America, testified on Capitol Hill before the United States Helsinki Commission. His Eminence and religious leaders of other traditions voiced their concern about the systematic efforts on the part of Turkey to undermine the Orthodox Church and the Ecumenical Patriarchate.

I cite, by way of example, the expropriation by Turkish authorities of properties of Christian Orthodox communities, the refusal by the Turkish Government to accord recognition as a legal entity to the Ecumenical Patriarchate, the shutdown of the Halki School of Theology and other attacks on religious minorities—Greek Orthodox, Armenian Orthodox, Roman Catholics, Jews.

For an impressive analysis of Turkish persecution of religious minorities, I refer you to the report issued only in May of this year by the United States Commission on International Religious Freedom.

And I could add the powerful statement on religious freedom made by Congressman Tom Lantos of California, chairman of the Committee on Foreign Affairs of the United States House of Representatives, also last May. Chairman Lantos sent a letter to Turkish Prime Minister Erdogan urging him to take several steps to liberalize Turkey's policies toward the Ecumenical Patriarchate, once and for all.

Forty-two of Chairman Lantos' Committee colleagues, Democrats and Republicans, signed the letter urging the Turkish Government to stop trying to bully the Ecumenical Patriarchate into extinction.

You here better than I can speak of the desecration of Greek Orthodox churches in Turkish-occupied Cyprus.

Let me conclude. As one who in the year 2001, in an address at the Bosphorous University in Turkey, said that I wanted to see a democratic Turkey, Turkey part of Europe and Turkey in the European Union, provided that country comply with the Copenhagen criteria, including respect for human rights, I must tell you that in 1974, when Paul Sarbanes, our colleagues and I in Congress voted an embargo on further American arms to Turkey, we made clear that for us this decision was a matter of respecting the rule of law—a point I have made earlier.

Paul Sarbanes and I, to repeat, were leaders of "The Rule of Law Lobby"!

Paul Sarbanes and I and many of our former colleagues in Congress—and I regret that I cannot include the present President of the United States in this regard—will continue to call on respect for the laws of our own country even as we will continue to urge justice for the brave people of Cyprus.

President Papadopoulos, thank you again for the great honor that you do Senator Sarbanes and me.

#### LANDMINES IN COLOMBIA

Mr. LEAHY. Mr. President, the people of Colombia have endured decades of civil conflict characterized by widespread killings and disappearances of civilians perpetrated by rebel groups and paramilitary death squads, sometimes with the active participation of government security forces. In recent